

RECEIVED

13 JUN 2007

EXPRESS MAIL LABEL NO.: EV980042854US  
DATE: June 13, 2007

Legal Staff  
International Division

PATENT  
TEVBNP 3.3-167

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of :  
Goller et al. :  
 :  
U.S. Application o.: 10/578,233 :  
 :  
 :  
International Application No. :  
PCT/US2004/036477 :  
 :  
 :  
International Filing Date: November 3, 2004 :  
 :  
 :  
For: SOFT STEROID COMPOSITIONS :  
FOR USE IN DRY POWDER :  
INHALERS :  
 :

Group Art Unit: Not Yet Assigned

Examiner: Not Yet Assigned

Date: June 13, 2007

MS PCT  
Commissioner for Patents  
Office of PCT Legal Admin.  
P.O. Box 1450  
Alexandria, VA 22313-1450

RESPONSE TO NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C.  
371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) AND  
PETITION UNDER 37 C.F.R. § 1.47(a)

Sir:

This is in response to the Notification Of Missing Requirements under 35 U.S.C. 371 In The United States Designated/Elected Office (DO/EO/US), dated November 13, 2006. A copy of the Notification is enclosed.

The present patent application names Michael I. Goller, Qi Li, Jade Ly, Mohammed Nurul Momin, Katherine Salas, Anayo Michael Ukeje, Ramesh Yanamandra and Xian-Ming Zeng as co-inventors. Statutory Declarations under 37 C.F.R. § 1.63, executed by Michael I. Goller, Jade Ly, Mohammed Nurul Momin, and Xian-Ming Zeng, are enclosed herewith. In accordance with MPEP § 409.03(a), the Declaration contains a signature block for all eight inventors. Co-Inventors Qi Li, Katherine Salas, Anayo Michael Ukeje, and Ramesh Yanamandra have not executed the enclosed declaration. Thus, Applicants respectfully submit the following information and documentation in support of this Petition Under 37 CFR § 1.47(a).

Pursuant to 37 C.F.R. § 1.47(a), the last known address of the non-signing inventors is as follows:

Qi Li, 7305 SW 129<sup>TH</sup> Street, Pincrest, Florida, 33156, United States of America

Katherine Salas, 1930 Collins Avenue, Apt. 217C, Sunny Isles Beach, Florida  
33160, United States of America

Anayo Michael Ukeje, 9 Nursery Close, Putney, London. SW15 6AS, United  
Kingdom

Ramesh Yanamandra, 34 Devon Drive, Chandlers Ford, Eastleigh, Hampshire  
SO53 3GN

The enclosed Exhibit A is an Affidavit of Samantha Claire Radley, Patent Administrator for Norton Healthcare Limited (the assignee of the present patent application), which states the facts relating to the diligent attempts she has made to obtain the signature of inventor Qi Li. In her Affidavit, Ms. Radley explains that on two separate occasions, she mailed to Qi Li, at his/her last known address, the application papers as filed, including the specification, drawings and claims. The Affidavit also sets forth the attempts she has made to locate Qi Li, including, re-mailing of the application papers, and contact with co-inventor Jade Ly. All attempts to locate and obtain the signature of Qi Li failed.

The enclosed Exhibit B is another Affidavit of Samantha Claire Radley, which states the facts relating to the diligent attempts she has made to obtain the signature of inventor Katherine Salas. In her Affidavit, Ms. Radley explains that on two separate occasions, she mailed to Ms. Salas, at her last known address, the application papers as filed, including the specification, drawings and claims. The Affidavit also sets forth the attempts made she made to locate Ms. Salas, including re-mailing of the application papers, and internet searches. All attempts to locate and obtain the signature of Ms. Salas failed.

The enclosed Exhibit C is another Affidavit of Samantha Claire Radley, which states the facts relating to the diligent attempts she has made to obtain the signature of inventor Anayo Ukeje. In her Affidavit, Ms. Radley explains that on two separate occasions, she mailed to Anayo Ukeje, at her/her last known address, the application papers as filed, including the specification, drawings and claims. The Affidavit also sets forth the attempts made she made to locate Anayo Ukeje, including re-mailing of the application papers, internet searches and contact with the

Application No. 10/578,233

Human Resources department of the assignee, Norton Healthcare Limited. All attempts to locate and obtain the signature of Anayo Ukeje failed.

The enclosed Exhibit D is another Affidavit of Samantha Claire Radley, which states the facts relating to the diligent attempts she has made to obtain the signature of inventor Ramesh Yanamandra. In her Affidavit, Ms. Radley explains that on two separate occasions, she mailed to Ramesh Yanamandra, at her/her last known address, the application papers as filed, including the specification, drawings and claims. The Affidavit also sets forth the attempts made she made to locate Ramesh Yanamandra, including re-mailing of the application papers, internet searches and contact with the Human Resources department of the assignee, Norton Healthcare Limited. All attempts to locate and obtain the signature of Ramesh Yanamandra failed.

The four Affidavits of Samantha Claire Radley are believed to establish that diligent efforts were made to contact the inventors and obtain their signatures on the Declaration.


It is respectfully submitted that the present Response and Petition, together with the documentation enclosed herewith, meet the requirements of 37 C.F.R. § 1.47(a). Acceptance of the captioned patent application under 37 C.F.R. § 1.47 is respectfully requested.

Further enclosed herewith is a Petition for extension of time to respond to the Notification Of Missing Requirements under 35 U.S.C. 371 In The United States Designated/Elected Office (DO/EO/US).

The Commissioner is hereby authorized to charge to our Deposit Account No. 12-1095: the petition fee pursuant to Rule 1.17(h) for the present Rule 47(a) Petition (\$130.00). In the event that any other fees are due in connection with this present petition, the Commissioner is hereby authorized to charge Deposit Account No. 12-1095 therefor.

Respectfully submitted,

LERNER, DAVID, LITTENBERG,  
KRUMHOLZ & MENTLIK, LLP

  
SHAWN P. FOLEY  
Reg. No. 33,071

600 South Avenue West  
Westfield, New Jersey 07090  
Telephone: (908) 654-5000  
Facsimile: (908) 654-7866  
775269\_1.DOC



## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

U.S. APPLICATION NUMBER NO.

10/578,233

FIRST NAMED APPLICANT

Michael I. Goller

ATTY. DOCKET NO.

TEVBNP33167

INTERNATIONAL APPLICATION NO.

PCT/US04/36477

I.A. FILING DATE

11/03/2004

PRIORITY DATE

11/03/2003

000530

LERNER, DAVID, LITTENBERG,  
KRUMHOLZ & MENTLIK  
600 SOUTH AVENUE WEST  
WESTFIELD, NJ 07090

CONFIRMATION NO. 7537

371 FORMALITIES LETTER



\*OC000000021195326\*

Date Mailed: 11/13/2006

### NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Copy of the International Application filed on 05/03/2006
- Copy of the International Search Report filed on 05/03/2006
- Information Disclosure Statements filed on 05/03/2006
- U.S. Basic National Fees filed on 05/03/2006
- Priority Documents filed on 05/03/2006

LDLK &amp;M

NOV 15 2006

RECEIVED

The applicant needs to satisfy supplemental fees problems indicated below.

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Additional claim fees of \$450 as a non-small entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due.
- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date.
- To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath or declaration) as set forth in 37 CFR 1.492(h) of \$130 for a non-small entity, must be submitted with the missing items identified in this letter.

## SUMMARY OF FEES DUE:

Total additional fees required for this application is \$580 for a Large Entity:

- **\$130** Surcharge.
- Total additional claim fee(s) for this application is **\$ 450**
  - **\$450** for **76** total claims over 20.

**ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.**

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web.  
<https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html>

For more information about EFS-Web please call the USPTO Electronic Business Center at **1-866-217-9197** or visit our website at <http://www.uspto.gov/ebc>.

**If you are not using EFS-Web to submit your reply, you must include a copy of this notice.**

CHARITTA A BURT

Telephone: (703) 308-9140 EXT 207

**PART 1 - ATTORNEY/APPLICANT COPY**

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
10/578,233	PCT/US04/36477	TEVBNP33167

Please type a plus sign (+) inside this box → ☐

PTO/SB/01 (03-01)

Approved for use through 10/31/2002. OMB 0651-0032  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

<b>DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION</b> <b>(37 CFR 1.63)</b>  <input type="checkbox"/> Declaration Submitted with Initial Filing    OR <input checked="" type="checkbox"/> Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)		Attorney Docket Number	TEVBNP 3.3-167
		First Named Inventor	Michael I. Goller
		<b>COMPLETE IF KNOWN</b>	
		Application Number	Not Yet Assigned
		Filing Date	Concurrently Herewith
		Group Art Unit	N/A
		Examiner Name	Not Yet Assigned

As a below named inventor, I hereby declare that:

My residence, mailing address, and citizenship are as stated below next to my name.

I believe I am an original and first inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled:

SOFT STEROID COMPOSITIONS FOR USE IN DRY POWDER INHALERS

(Title of the Invention)

the specification of which

☐ is attached hereto

OR

☒ was filed on (MM/DD/YYYY) 11/03/2004 as United States Application Number or PCT International

Application No. PCT/US2004/036477 and was amended on (MM/DD/YYYY) (if applicable)

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.58, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT International filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or (f), or 365(b) of any foreign application(s) for patent, inventor's or plant breeder's rights certificate(s); or 365 (a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent, inventor's or plant breeder's rights certificate(s), or of any PCT International application having a filing date before that of the application on which priority is claimed:

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached?	
				YES	NO
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

Please type a plus sign (+) inside this box. → ☐

PTO/SB/01 (03-01)  
Approved for use through 10/31/2002. OMB 0851-0032  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE  
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

## DECLARATION — Utility or Design Patent Application

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following registered practitioner(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith: Customer Number 000530.

Direct all correspondence to: ☒ Customer Number or Bar Code Label **000530** OR ☐ Correspondence address below

Name

Address

City

State

ZIP

Country

Telephone

Email

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

NAME OF SOLE OR FIRST INVENTOR:

☐ A petition has been filed for this unsigned inventor

Given Name  
(first and middle (if any))

Michael I.

Family Name  
or Surname

Goller

Inventor's  
Signature

*M2 Goller*

Date

*24 May 2007*

Residence: City

London

State

United Kingdom

Citizenship

United Kingdom

Mailing  
Address:

84 Faringford Road  
Stratford

City

London

State

E14 4DW

Country

United Kingdom

NAME OF SECOND INVENTOR:

☐ A petition has been filed for this unsigned inventor

Given Name  
(first and middle (if any))

Qi

Family Name  
or Surname

Li

Inventor's  
Signature

*Qi*

Date

*US*

Residence: City

Pinecrest

State

United States of  
America

Citizenship

US

Mailing  
Address:

7305 SW 129th Street

City

Pinecrest

State

FL

ZIP

United States of America

☒

Additional inventors are being named on the 2 supplemental Additional Inventor(s) sheet(s) PTO/SB/02A attached hereto.

LD-837A

Please type a plus sign (+) inside this box ☐

PTO/SB/01 (03-01)  
Approved for use through 10/31/2002. OMB 0651-0032  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

**DECLARATION FOR UTILITY OR  
DESIGN  
PATENT APPLICATION  
(37 CFR 1.63)**

☐ Declaration Submitted with Initial Filing OR ☒ Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)

Attorney Docket Number TEVBNP 3.3-167

First Named Inventor Michael I. Goller

**COMPLETE IF KNOWN**

Application Number Not Yet Assigned

Filing Date Concurrently Herewith

Group Art Unit N/A

Examiner Name Not Yet Assigned

**As a below named inventor, I hereby declare that:**

My residence, mailing address, and citizenship are as stated below next to my name.

I believe I am an original and first inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled:

SOFT STEROID COMPOSITIONS FOR USE IN DRY POWDER INHALERS

(Title of the Invention)

the specification of which

☐ is attached hereto  
OR

☒ was filed on (MM/DD/YYYY) 11/03/2004 as United States Application Number or PCT International

Application No. PCT/US2004/036477 and was amended on (MM/DD/YYYY) (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or (f), or 365(b) of any foreign application(s) for patent, inventor's or plant breeder's rights certificate(s), or 365 (a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent, inventor's or plant breeder's rights certificate(s), or of any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached?	
				YES	NO
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

<b>DECLARATION</b>		<b>ADDITIONAL INVENTOR(S) Supplemental Sheet</b>	
		Page <u>1</u> of <u>2</u>	
<b>Name of Additional Joint Inventor, if any:</b>		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))		Family Name or Surname	
Jade		Ly	
Inventor's Signature <i>Jade Ly</i>		Date <i>8-9-06</i>	
Residence: City	State	Country	Citizenship
Cooper City	FL	United States of America	People's Republic of China
Mailing Address: 4740 Hibbs Grove Terrace			
City	State	Zip	Country
Cooper City	FL	33330	United States of America
<b>Name of Additional Joint Inventor, if any:</b>		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))		Family Name or Surname	
Mohammed Nurul		Momin	
Inventor's Signature		Date	
Residence: City	State	Country	Citizenship
London		United Kingdom	United Kingdom
Mailing Address: 19 Welstead House, Cannon Street Road			
City	State	Zip	Country
London		E1 2LJ	United Kingdom
<b>Name of Additional Joint Inventor, if any:</b>		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))		Family Name or Surname	
Katherine		Salas	
Inventor's Signature		Date	
Residence: City	State	Country	Citizenship
Sunny Isles Beach	FL	United States of America	US
Mailing Address: 19370 Collins Avenue Apt. 217C			
City	State	Zip	Country
Sunny Isles Beach	FL	33160	United States of America
<b>Name of Additional Joint Inventor, if any:</b>		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))		Family Name or Surname	
Anayo Michael		Ukeje	
Inventor's Signature		Date	
Residence: City	State	Country	Citizenship
London		United Kingdom	Nigeria
Mailing Address: 9 Nursery Close Putney			
City	State	Zip	Country
London		SW15 6AS	United Kingdom

Please type a plus sign (+) inside this box ☐

PTO/SB/01 (03-01)  
Approved for use through 10/31/2002. OMB 0851-0032  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

**DECLARATION FOR UTILITY OR  
DESIGN  
PATENT APPLICATION  
(37 CFR 1.63)**

☐ Declaration  
Submitted  
with Initial  
Filing

OR

☒ Declaration  
Submitted after Initial  
Filing (surcharge  
(37 CFR 1.16 (e))  
required)

Attorney Docket Number TEVBNP 3.3-167

First Named Inventor Michael I. Goller

**COMPLETE IF KNOWN**

Application Number Not Yet Assigned

Filing Date Concurrently Herewith

Group Art Unit N/A

Examiner Name Not Yet Assigned

**As a below named inventor, I hereby declare that:**

My residence, mailing address, and citizenship are as stated below next to my name.

I believe I am an original and first inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled:

SOFT STEROID COMPOSITIONS FOR USE IN DRY POWDER INHALERS

(Title of the invention)

the specification of which

☐ Is attached hereto  
OR

☒ was filed on (MM/DD/YYYY) 11/03/2004 as United States Application Number or PCT International

Application No. PCT/US2004/036477 and was amended on (MM/DD/YYYY) (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or (f), or 365(b) of any foreign application(s) for patent, inventor's or plant breeder's rights certificate(s), or 365 (a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent, inventor's or plant breeder's rights certificate(s), or of any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed		Certified Copy Attached?	
			YES	NO	YES	NO
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

<b>DECLARATION</b>				<b>ADDITIONAL INVENTOR(S) Supplemental Sheet</b>	
				Page <u>1</u> of <u>2</u>	
Name of Additional Joint Inventor, if any:			<input type="checkbox"/> A petition has been filed for this unsigned inventor		
Given Name (first and middle (if any))			Family Name or Surname		
Jade			Ly		
Inventor's Signature			Date		
Residence: City		State	Country		Citizenship
Cooper City		FL	United States of America		People's Republic of China
Mailing Address: 4740 Hibbs Grove Terrace					
City		State	Zip		Country
Cooper City		FL	33330		United States of America
Name of Additional Joint Inventor, if any:			<input type="checkbox"/> A petition has been filed for this unsigned inventor		
Given Name (first and middle (if any))			Family Name or Surname		
Mohammed Nurul			Momin		
Inventor's Signature			Date		
Residence: City		State	Country		Citizenship
London			United Kingdom		United Kingdom
Mailing Address: 19 Welstead House, Cannon Street Road					
City		State	Zip		Country
London			E1 2LJ		United Kingdom
Name of Additional Joint Inventor, if any:			<input type="checkbox"/> A petition has been filed for this unsigned inventor		
Given Name (first and middle (if any))			Family Name or Surname		
Katherine			Salas		
Inventor's Signature			Date		
Residence: City		State	Country		Citizenship
Sunny Isles Beach		FL	United States of America		US
Mailing Address: 19370 Collins Avenue Apt. 217C					
City		State	Zip		Country
Sunny Isles Beach		FL	33160		United States of America
Name of Additional Joint Inventor, if any:			<input type="checkbox"/> A petition has been filed for this unsigned inventor		
Given Name (first and middle (if any))			Family Name or Surname		
Anayo Michael			Ukeje		
Inventor's Signature			Date		
Residence: City		State	Country		Citizenship
London			United Kingdom		Nigeria
Mailing Address: 9 Nursery Close Putney					
City		State	Zip		Country
London			SW15 6AS		United Kingdom

Please type a plus sign (+) inside this box ☐

PTO/SB/01 (03-01)  
Approved for use through 10/31/2002. OMB 0651-0032  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE  
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

<b>DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION</b> (37 CFR 1.63)	<b>Attorney Docket Number</b>	TEVBNP 3.3-167
	<b>First Named Inventor</b>	Michael I. Goller
	<b>COMPLETE IF KNOWN</b>	
	<b>Application Number</b>	Not Yet Assigned
	<b>Filing Date</b>	Concurrently Herewith
	<b>Group Art Unit</b>	N/A
<input type="checkbox"/> Declaration Submitted with Initial Filing	<b>OR</b>	<input checked="" type="checkbox"/> Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)
<b>Examiner Name</b>		Not Yet Assigned

**As a below named Inventor, I hereby declare that:**

My residence, mailing address, and citizenship are as stated below next to my name.

I believe I am an original and first inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled:

SOFT STEROID COMPOSITIONS FOR USE IN DRY POWDER INHALERS

(Title of the Invention)

the specification of which

☐ is attached hereto  
**OR**

☒ was filed on (MM/DD/YYYY) 11/03/2004 as United States Application Number or PCT International

Application No. PCT/US2004/036477 and was amended on (MM/DD/YYYY) (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or (f), or 365(b) of any foreign application(s) for patent, inventor's or plant breeder's rights certificate(s), or 365 (a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent, inventor's or plant breeder's rights certificate(s), or of any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached?	
				YES	NO
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

**DECLARATION****ADDITIONAL INVENTOR(S)  
Supplemental Sheet**

Page 2 of 2

<b>Name of Additional Joint Inventor, if any:</b>		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))		Family Name or Surname	
Ramesh		Yanamandra	
Inventor's Signature		Date	
Residence: City	State	Country	Citizenship
London		United Kingdom	India
Mailing Address: 15 Barry Road Beckton			
City	State	Zip	Country
London		E6 5TA	United Kingdom
<b>Name of Additional Joint Inventor, if any:</b>		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))		Family Name or Surname	
Xian-Ming		Zeng	
Inventor's Signature <i>X M Zeng</i>		Date <i>13 Oct 2006</i>	
Residence: City	State	Country	Citizenship
Surrey		United Kingdom	<del>People's Republic of China</del> BRITISH
Mailing Address: 45 Hill Road Mitcham			
City	State	Zip	Country
Surrey		CR4 2HS	United Kingdom
<b>Name of Additional Joint Inventor, if any:</b>		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))		Family Name or Surname	
Inventor's Signature		Date	
Residence: City	State	Country	Citizenship
Mailing Address:			
City	State	Zip	Country
<b>Name of Additional Joint Inventor, if any:</b>		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))		Family Name or Surname	
Inventor's Signature		Date	
Residence: City	State	Country	Citizenship
Mailing Address:			
City	State	Zip	Country

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a) FY 2006 (Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).)		Docket Number (Optional) TEVBNP 3.3-167	
Application Number	10/578,233	Filed	May 3, 2006
For SOFT STERIOD COMPOSITIONS FOR USE IN DRY POWDER INHALERS			
Art Unit	N/A	Examiner	Not Yet Assigned
This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above identified application. The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):			
		<u>Fee</u>	<u>Small Entity Fee</u>
<input type="checkbox"/>	One month (37 CFR 1.17(a)(1))	\$120	\$60
<input type="checkbox"/>	Two months (37 CFR 1.17(a)(2))	\$450	\$225
<input type="checkbox"/>	Three months (37 CFR 1.17(a)(3))	\$1020	\$510
<input type="checkbox"/>	Four months (37 CFR 1.17(a)(4))	\$1590	\$795
<input checked="" type="checkbox"/>	Five months (37 CFR 1.17(a)(5))	\$2160	\$1080
<input type="checkbox"/>	Applicant claims small entity status. See 37 CFR 1.27.		
<input type="checkbox"/>	A check in the amount of the fee is enclosed.		
<input type="checkbox"/>	Payment by credit card. Form PTO-2038 is attached.		
<input checked="" type="checkbox"/>	The Director has already been authorized to charge fees in this application to a Deposit Account.		
<input checked="" type="checkbox"/>	The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number <u>12-1095</u> . I have enclosed a duplicate copy of this sheet.		
I am the	<input type="checkbox"/>	applicant/inventor.	
	<input type="checkbox"/>	assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96).	
	<input checked="" type="checkbox"/>	attorney or agent of record. Registration Number <u>33,071</u>	
	<input type="checkbox"/>	attorney or agent under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____	
<u>Shawn P. Foley</u> Signature		<u>June 13, 2007</u> Date	
<u>Shawn P. Foley</u> Typed or printed name		<u>(908) 518-6346</u> Telephone Number	
NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.			
<input type="checkbox"/>	Total of <u>1</u> forms are submitted.		

RECEIVED

13 JUN 2007

Legal Staff  
International Division

# COPY

PTO/SB/22 (04-07)

Approved for use through 09/30/2007. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

<b>PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a) FY 2006</b> (Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).)		Docket Number (Optional) TEVBNP 3.3-167																									
Application Number 10/578,233		Filed May 3, 2006																									
For <b>SOFT STEROID COMPOSITIONS FOR USE IN DRY POWDER INHALERS</b>																											
Art Unit N/A		Examiner Not Yet Assigned																									
<p>This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above identified application.</p> <p>The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):</p> <table style="width: 100%; border-collapse: collapse;"><thead><tr><th></th><th style="text-align: center;"><u>Fee</u></th><th style="text-align: center;"><u>Small Entity Fee</u></th><th></th></tr></thead><tbody><tr><td><input type="checkbox"/> One month (37 CFR 1.17(a)(1))</td><td style="text-align: center;">\$120</td><td style="text-align: center;">\$60</td><td>\$ _____</td></tr><tr><td><input type="checkbox"/> Two months (37 CFR 1.17(a)(2))</td><td style="text-align: center;">\$450</td><td style="text-align: center;">\$225</td><td>\$ _____</td></tr><tr><td><input type="checkbox"/> Three months (37 CFR 1.17(a)(3))</td><td style="text-align: center;">\$1020</td><td style="text-align: center;">\$510</td><td>\$ _____</td></tr><tr><td><input type="checkbox"/> Four months (37 CFR 1.17(a)(4))</td><td style="text-align: center;">\$1590</td><td style="text-align: center;">\$795</td><td>\$ _____</td></tr><tr><td><input checked="" type="checkbox"/> Five months (37 CFR 1.17(a)(5))</td><td style="text-align: center;">\$2160</td><td style="text-align: center;">\$1080</td><td>\$ <u>2,160.00</u></td></tr></tbody></table> <p><input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27.</p> <p><input type="checkbox"/> A check in the amount of the fee is enclosed.</p> <p><input type="checkbox"/> Payment by credit card. Form PTO-2038 is attached.</p> <p><input checked="" type="checkbox"/> The Director has already been authorized to charge fees in this application to a Deposit Account.</p> <p><input checked="" type="checkbox"/> The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number <u>33-1095</u>. <del>I have enclosed a duplicate copy of this sheet.</del></p> <p>I am the <input type="checkbox"/> applicant/inventor.</p> <p><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96).</p> <p><input checked="" type="checkbox"/> attorney or agent of record. Registration Number <u>33,071</u></p> <p><input type="checkbox"/> attorney or agent under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____</p> <p><u>Shawn P. Foley</u> _____ Signature</p> <p><u>Shawn P. Foley</u> _____ Typed or printed name</p> <p>_____ June 13, 2007 Date</p> <p>_____ (908) 518-6346 Telephone Number</p> <p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.</p> <p><input type="checkbox"/> Total of <u>1</u> forms are submitted.</p>					<u>Fee</u>	<u>Small Entity Fee</u>		<input type="checkbox"/> One month (37 CFR 1.17(a)(1))	\$120	\$60	\$ _____	<input type="checkbox"/> Two months (37 CFR 1.17(a)(2))	\$450	\$225	\$ _____	<input type="checkbox"/> Three months (37 CFR 1.17(a)(3))	\$1020	\$510	\$ _____	<input type="checkbox"/> Four months (37 CFR 1.17(a)(4))	\$1590	\$795	\$ _____	<input checked="" type="checkbox"/> Five months (37 CFR 1.17(a)(5))	\$2160	\$1080	\$ <u>2,160.00</u>
	<u>Fee</u>	<u>Small Entity Fee</u>																									
<input type="checkbox"/> One month (37 CFR 1.17(a)(1))	\$120	\$60	\$ _____																								
<input type="checkbox"/> Two months (37 CFR 1.17(a)(2))	\$450	\$225	\$ _____																								
<input type="checkbox"/> Three months (37 CFR 1.17(a)(3))	\$1020	\$510	\$ _____																								
<input type="checkbox"/> Four months (37 CFR 1.17(a)(4))	\$1590	\$795	\$ _____																								
<input checked="" type="checkbox"/> Five months (37 CFR 1.17(a)(5))	\$2160	\$1080	\$ <u>2,160.00</u>																								

Express Mail Label No. EV980042854US Dated: June 12, 2007

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

13 JUN 2007

In re Patent Application of	:	
Goller et al.	:	
	:	
U.S. Application o.: 10/578,233	:	Group Art Unit: Not Yet Assigned
	:	
International Application No.	:	
PCT/US2004/036477	:	
	:	
International Filing Date: November 3, 2004:	:	Examiner: Not Yet Assigned
	:	
For: SOFT STEROID COMPOSITIONS	:	Date: June 13, 2007
FOR USE IN DRY POWDER	:	
INHALERS	:	
	:	

MS PCT  
Commissioner for Patents  
Office of PCT Legal Admin.  
P.O. Box 1450  
Alexandria, VA 22313-1450  
  
Attention: Charitta A. Burt

COMMUNICATION

Sir:

In response to the Notification of Missing Requirements Under 35 U.S.C. 371 in the United States Designated/Elected Office (DO/EO/US) dated November 13, 2006, (a copy of which is enclosed herewith), please note that upon review of the claims with Charitta A. Burt, it was determined that that Claim 8 and Claim 10 are improper and should not have been counted as a multiple dependent claims and the additional revised claim fee of \$150.00 is enclosed.

Accordingly, it is believed that this case is in good order. A preliminary amendment correcting the numbering will be submitted by applicant's attorney. If the Examiner has any questions concerning this matter, he is requested to call applicant's




attorney at (908) 654-5000. If there are any additional fees, please charge them to our  
Deposit Account No. 12-1095.

Date: June 13, 2007

Respectfully submitted,

LERNER, DAVID, LITTENBERG,  
KRUMHOLZ & MENTLIK LLP

  
SHAWN P. FOLEY  
Reg. No. 33,071

600 South Avenue West  
Westfield, New Jersey 07090-1497  
(908) 654-5000

EXPRESS MAIL LABEL NO.: EL980042854US

Filed on behalf of Norton Healthcare Limited

Deponent: S. C. Radley

First Affidavit of the Deponent

Date of Swearing: 8 June 2007

Exhibits: SR1-2

IN THE MATTER of United States Patent Application Number 10/578,233

---

AFFIDAVIT OF SAMANTHA CLAIRE RADLEY

---

I, SAMANTHA CLAIRE RADLEY, of 79a Gellatly Road, London SE14 5TU  
Patent Administrator, MAKE OATH and say as follows:

1. I am a Patent Administrator for Norton Healthcare Limited ("Norton") and I make this affidavit in support of Norton's United States patent application number 10/578,233 entitled "Soft Steroid Compositions for Use in Dry Powder Inhalers". In so far as the content of this affidavit is within my personal knowledge it is true, and so far as it is not within my personal knowledge it is true to the best of my knowledge information and belief.
2. On 3 August 2006, I sent a bundle of documents consisting of a Declaration for Utility or Design Patent Application, a copy of US Patent Application No. 10/578,233 and an Assignment of Utility Application form to 7305 SW 129<sup>th</sup> Street, Pinecrest, Florida 33156, U.S.A, the address of Qi Li detailed in the PCT application, PCT/US2004/036477. The documents were never returned to me at Norton Healthcare Ltd.
3. On 1<sup>st</sup> March 2007, I sent the bundle of documents described in paragraph 2 above to 7305 SW 129<sup>th</sup> Street, Pinecrest, Florida 33156, U.S.A by special delivery. The package was returned to me as Qi Li was unknown at the given address. I present the envelope and contents as Exhibit "SR1".
4. On the 18<sup>th</sup> May 2007, I asked Colleen Maroney of the US Law Firm Lerner David Littenberg Krumholz & Menklik to search for Qi Li. Colleen Maroney responded on the 24<sup>th</sup> May 2007 and advised that the address for Qi Li was the same as that shown on the PCT application but as the package described in paragraph 3 was returned to me, Qi Li had moved without changing the details. I present the email of 24<sup>th</sup> May 2007 as Exhibit "SR2".
5. On 6<sup>th</sup> June 2007, I spoke to another of the named inventors, Jade Ly, who confirmed that Qi Li had moved away from the address detailed in paragraph 3 but she did not know his current address.
6. It is my belief that I cannot contact Qi Li to obtain his signature at this time.

Sworn at 62-65  
CHANDOS PLACE  
LONDON ENGLAND  
WC2N 4LP  
this 8 day of  
JUNE 2007



Signature of Deponent making the Affidavit

Before me,

KIRSTEN JANET  
DUNLOP  
SOLICITOR



Signature of Authorised Witness

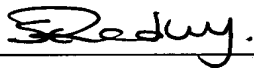
Shepherd and Wedderburn LLP  
Condor House  
10 St. Paul's Churchyard  
LONDON  
EC4M 8AL

IN THE MATTER of United States Patent Application Number 10/578,233

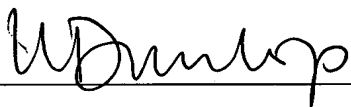
---

EXHIBIT SR1 TO THE  
AFFIDAVIT OF SAMANTHA CLAIRE RADLEY

---

A handwritten signature in cursive script, appearing to read "S. Radley", is written over a horizontal line.

SAMANTHA CLAIRE RADLEY

A handwritten signature in cursive script, appearing to read "W. Dunlop", is written over a horizontal line.

PRACTISING SOLICITOR



Subsidiary of **IVAX** Corporation

Albert Basin, Royal Docks  
London E16 2QJ

Telephone 08705 02 03 04  
Fax 08705 32 33 34

Qi Li  
7305 SW 129<sup>th</sup> Street  
Pinecrest  
Florida 33156  
U.S.A.

1<sup>st</sup> March 2007

Dear Qi,

RE: US National Phase of PCT/2004/36477 for  
SOFT STEROID COMPOSITIONS FOR USE IN DRY POWDER INHALERS  
in the name of Norton Healthcare Limited

Please find enclosed a declaration for use in the prosecution of the above United States patent application by Norton Healthcare Limited.

Please can you sign and date the declaration where indicated and return it to me at the below address as quickly as possible.

Thanks for your help.

Yours sincerely

Mrs Samantha Radley  
Patent Administrator  
Teva Europe Patent Department  
3rd Floor  
Brookmount House  
62-65 Chandos Place  
London WC2N 4LP  
Tel: 020 7540 7242  
Fax: 020 7540 7029  
email: [samantha.radley@tevaeu.com](mailto:samantha.radley@tevaeu.com)

Please type a plus sign (+) inside this box ☐

PTO/SB/01 (03-01)  
Approved for use through 10/31/2002. OMB 0651-0032  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

**DECLARATION FOR UTILITY OR  
DESIGN  
PATENT APPLICATION  
(37 CFR 1.63)**

☐ Declaration Submitted with Initial Filing OR ☒ Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)

Attorney Docket Number TEVBNP 3.3-167

First Named Inventor Michael I. Goller

**COMPLETE IF KNOWN**

Application Number Not Yet Assigned

Filing Date Concurrently Herewith

Group Art Unit N/A

Examiner Name Not Yet Assigned

**As a below named inventor, I hereby declare that:**

My residence, mailing address, and citizenship are as stated below next to my name.

I believe I am an original and first inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled:

SOFT STEROID COMPOSITIONS FOR USE IN DRY POWDER INHALERS

(Title of the Invention)

the specification of which

☐ is attached hereto  
OR

☒ was filed on (MM/DD/YYYY) 11/03/2004 as United States Application Number or PCT International

Application No. PCT/US2004/036477 and was amended on (MM/DD/YYYY) (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or (f), or 365(b) of any foreign application(s) for patent, inventor's or plant breeder's rights certificate(s), or 365 (a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent, inventor's or plant breeder's rights certificate(s), or of any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached?	
				YES	NO
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

Please type a plus sign (+) inside this box



PTO/SB/01 (03-01)  
Approved for use through 10/31/2002. OMB 0651-0032  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

## DECLARATION — Utility or Design Patent Application

**POWER OF ATTORNEY:** As a named inventor, I hereby appoint the following registered practitioner(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith: Customer Number 000530

Direct all correspondence to:		<input checked="" type="checkbox"/> Customer Number or Bar Code Label	000530		OR <input type="checkbox"/> Correspondence address below
Name					
Address					
City		State		ZIP	
Country		Telephone		Email	
I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.					
NAME OF SOLE OR FIRST INVENTOR:				<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle [if any])		Michael I.		Family Name or Surname Goller	
Inventor's Signature				Date	
Residence: City		State		Country	
London		United Kingdom		United Kingdom	
Mailing Address:		84 Faringford Road Stratford			
City		State		Country	
London		E14 4DW		United Kingdom	
NAME OF SECOND INVENTOR:				<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle [if any])		Qi		Family Name or Surname Li	
Inventor's Signature				Date	
Residence: City		State		Country	
Pincrest		FL		United States of America	
Mailing Address:		7305 SW 129th Street			
City		State		Country	
Pincrest		33156		United States of America	
<input checked="" type="checkbox"/> Additional inventors are being named on the 2 supplemental Additional Inventor(s) sheet(s) PTO/SB/02A attached hereto.					

LD-537A